k081685

5.0 510(k) SUMMARY

NOV 18 2008

SUBMITTED BY:

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NAME OF DEVICE

Trade Name: LIAISON® HSV-1 Type Specific IgG
LIAISON® Control HSV-1 IgG

Common Names/Descriptions: Immunoassay for the detection of specific IgG antibodies to Herpes Simplex Virus Type 1 (HSV-1) in human serum samples.

Classification Names: Herpes Simplex Virus Serological Reagents

Product Code: MXJ, JJX

PREDICATE DEVICES: Focus Diagnostics HerpeSelect® 1 and 2 Immunoblot IgG (K000238)

DEVICE DESCRIPTION:

INTENDED USE:

The LIAISON® HSV-1 Type Specific IgG assay is a chemiluminescent immunoassay to be used with the LIAISON® Analyzer for the qualitative determination of type specific IgG antibodies to Herpes simplex virus Type 1 (HSV-1) in human serum.
The assay is indicated for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-1 infection.

The LIAISON® HSV-1 Type Specific IgG assay has not been established for use in the pediatrics population, for neonatal screening, or for testing immunocompromised patients. The assay is neither FDA cleared nor approved for testing blood or plasma donors.

The LIAISON® Control HSV-1 (negative and positive) are intended for use as assayed quality control samples to monitor the performance of the LIAISON® HSV-1 Type Specific IgG assay.

KIT DESCRIPTION:
The method for qualitative determination of specific IgG to HSV-1 is an indirect chemiluminescence immunoassay (CLIA). HSV-1 gG1recombinant antigen is used for coating magnetic particles (solid phase) and a mouse monoclonal antibody is linked to an isoluminol derivative (isoluminol-antibody conjugate). During the first incubation, HSV-1 antibodies present in calibrators, samples or controls bind to the solid phase. During the second incubation, the antibody conjugate reacts with HSV-1 IgG already bound to the solid phase. After each incubation the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is indicative of HSV-1 IgG present in calibrators, samples or controls.

PERFORMANCE DATA:
COMPARATIVE CLINICAL TRIALS:
Studies were conducted which compared the LIAISON® HSV-1 Type Specific IgG assay to an FDA cleared Immunoblot. The studies were conducted on 951 samples collected in the Northeastern United States. The samples were classified as "At risk" samples (n=401) from Sexually Active Adults (at risk for a Sexually Transmitted Disease), Expectant Mothers (n=430) and a Low Prevalence population (n=120) from patients seen at the clinic for anything other than an STD. The studies were conducted at two (2) independent external laboratories.

The sample populations were divided between site 1 and site 2 for LIAISON® HSV-1 testing. Site 1 tested a total of 460 samples (201 Sexually Active Adults, 199 Expectant Mothers and 60 Low Prevalence). Site 2 tested a total of 491 samples (200 Sexually Active Adults, 231 Expectant Mothers and 60 Low Prevalence). Site 3 tested a total of 951 samples (401 Sexually Active Adults, 430 Expectant Mothers and 120 Low Prevalence) with the FDA cleared Immunoblot.
Equivocal samples were repeat tested as per the Instructions for Use. Any repeat Equivocal samples on the predicate device were sent to a Reference Laboratory in the Pacific Northwest for Western Blot testing. The Western Blot results are included in the tables. All results are expressed as sensitivity and specificity with exact 95% Confidence Intervals.

Sexually Active Adults (401)
Four Hundred one (401) samples were obtained from Sexually Active Adults who were seen at STD clinics in the Northeastern US were tested with the LIAISON® HSV-1 Type Specific IgG assay and the HSV-1 predicate method Immunoblot. Results are summarized below.

LIAISON® HSV-1 Type Specific IgG	Predicate Device			Total
	Positive	Equivocal	Negative	
Positive	222	1	12	235
Equivocal	0	0	2	2
Negative	7	0	157	164
Total	229	1*	171	401

	Percent	95% Confidence Intervals
Sensitivity	96.9% (222/229)	94.3 – 98.6%
Specificitiy	91.3% (157/172)	86.9 – 94.6%

* This sample was Indeterminate with Western Blot testing

Expectant Mother Population (430)

Four hundred thirty (430) samples collected from Expectant Mothers in the Northeastern US were tested with the LIAISON® HSV-1 Type Specific IgG assay and the HSV-1 predicate method Immunoblot. Results are summarized below.

LIAISON® HSV-1 Type Specific IgG	Predicate Device			Total
	Positive	Equivocal	Negative	
Positive	236	0	10	246
Equivocal	0	0	2	2
Negative	3	0	179	182
Total	239	0	191	430

	Percent	95% Confidence Intervals
Sensitivity	98.7% (236/239)	96.8 – 99.7%
Specificity	93.7% (179/191)	90.0 – 96.3%

Low Prevalance Population (120)

One hundred twenty (120) "Low Prevalence" samples obtained from individuals who were seen at clinics (not for STD) in the Northeastern US were tested with the LIAISON® HSV-1 Type Specific IgG assay and the HSV-1 predicate method Immunoblot. Results are summarized below.

LIAISON® HSV-1 Type Specific IgG	Predicate Device			Total
	Positive	Equivocal	Negative	
Positive	60	0	0	60
Equivocal	1	0	0	1
Negative	1	0	58	59
	62	0	58	120

	Percent	95% Confidence Intervals
Sensitivity	96.8% (60/62)	90.1 - 99.4%
Specificity	100.0% (58/58)	94.9 – 100.0%

CDC PANEL:
A serum panel was obtained from the Centers for Disease Control and Prevention and tested by the LIAISON® HSV-1 Type Specific IgG assay. The results are presented as a means of conveying further information on the performance of this assay with a characterized serum panel. This does not imply an endorsement of the assay by the CDC.

The panel consisted of 52% positive and 48% negative samples. The LIAISON® HSV-1 Type Specific IgG assay demonstrated 100% positive agreement with the CDC positive results (52/52) and 93.75% negative agreement with the CDC negative results (45/48). There were three false positive results obtained with the Liaison HSV-1 Type specific assay.

Conclusion: The LIAISON® HSV-1 Type Specific IgG showed equivalent performance to the FDA cleared comparison method.
The results demonstrate that the LIAISON® HSV-1 Type Specific IgG assay can be used with the LIAISON® Analyzer for the qualitative determination of specific IgG antibodies to Herpes Simplex Virus Type 1 in human serum samples.

EXPECTED VALUES:
The prevalence may vary depending upon geographical location, age, gender, type of test employed, specimen collection and handling procedures as well as clinical history of the patient.
The observed and the hypothetical predictive values for the sexually active adults, expectant mothers, and low prevalence populations are shown below. The positive predictive value (PPV) will decrease proportionally to the prevalence of HSV-1 infection as reflected in the table. The calculations are based on LIAISON® HSV-1 positive and negative agreements of 96.9% and 91.3%, respectively, in a sexually active adult population, 98.7% and 93.7%, respectively, in an expectant mothers population, and 96.8% and 100%, respectively, in a low prevalence population.

Population	Sero-Status	Observed Prevalence	
		LIAISON	Predicate
Sexually Active Adults[a]	HSV-1 Negative	41.0% (164/400)	42.8% (171/400)
	HSV-1 Positive	58.5% (234/400)	57.3% (229/400)
Expectant Mothers[b]	HSV-1 Negative	42.5% (182/428)	44.2% (189/428)
	HSV-1 Positive	57.5% (246/428)	55.8% (239/428)
Low Prevalence[c]	HSV-1 Negative	49.6% (59/119)	48.7% (58/119)
	HSV-1 Positive	50.4% (60/119)	51.3% (61/119)

[a] Excludes 1 Indeterminate by Predicate
[b] Excludes 2 Equivocal by LIAISON
[c] Excludes 1 Equivocal by LIAISON

HSV-1 Prevalence vs. Hypothetical Predictive Values

Prevalence	Sexually Active Adults		Expectant Mothers		Low Prevalence	
	PPV	NPV	PPV	NPV	PPV	NPV
80%	97.8%	88.0%	98.4%	94.7%	100%	88.7%
70%	96.3%	92.7%	97.3%	96.9%	100%	93.1%
60%	94.4%	95.2%	95.9%	98.0%	100%	95.4%
50%	91.8%	96.7%	94.0%	98.6%	100%	96.9%
40%	88.1%	97.8%	91.3%	99.1%	100%	97.9%
30%	82.7%	98.6%	87.0%	99.4%	100%	98.6%
20%	73.6%	99.2%	79.7%	99.7%	100%	99.2%
10%	55.3%	99.6%	63.5%	99.8%	100%	99.6%

REPRODUCIBILITY:

A reproducibility/precision study was conducted at two external laboratories and at DiaSorin Inc. This study included 3 LIAISON® HSV-1 Type Specific IgG Specific IgG Reagent Integral kit lots and 3 LIAISON® Analyzers. Each site used a different lot of the LIAISON® HSV-1 Type Specific IgG for the study.

A coded panel comprised of 8 frozen "engineered" serum samples was prepared by DiaSorin Inc. and provided to the sites. The coded panel samples were prepared using neat positive serum or by blending positive and negative serum samples to achieve high negative, equivocal, low positive and high positive results. The LIAISON® Control HSV-1 set were also included in the 5 day study. All panel members were divided into aliquots and stored frozen prior to testing. The CLSI document EP15-A2 was consulted in the preparation of the testing protocol.

The coded panel was tested at all three sites, using four replicates per run in two runs per day with different operators performing each run during five operating days. The mean, standard deviation, and coefficient of variation (%CV) of the results were computed for each of the tested specimens for each of the sites and across sites.

Sample ID	N	Mean Index	Within run %CV	Between run %CV	Total (by site) %CV	Between site %CV	Overall SD	Overall %CV
NC	120	0.15	4.3	5.3	7.0	14.4	0.02	14.9
PC	120	2.31	3.6	5.6	6.2	11.2	0.28	12.0
HSV1A	120	1.92	5.2	7.5	8.3	10.6	0.25	12.9
HSV1B	120	1.29	2.6	5.7	5.9	13.5	0.18	13.8
HSV1C	120	1.09	2.4	4.7	5.1	12.5	0.14	12.7
HSV1D	120	63.8	3.8	4.7	6.4	8.4	6.43	10.1
HSV1E	120	0.85	2.7	4.8	5.2	10.8	0.10	11.3
HSV1F	120	0.88	2.8	5.7	6.1	11.6	0.11	12.3
HSV1G	120	1.20	4.1	6.6	7.9	12.8	0.17	14.4
HSV1H	120	1.35	3.4	5.8	6.7	13.6	0.19	14.3

CONCLUSION:

The material submitted in this premarket notification is complete and supports a substantial equivalence decision. The labeling is sufficient and it satisfies the requirements of 21CFR 809.10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Ms. Carol DePouw
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NOV 18 2008

Re: K081685
Trade/Device Name: LIAISON® HSV-1 Type Specific IgG Assay
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes Simplex Virus serological reagents
Regulatory Class: Class II
Product Code: MXJ, JJX
Dated: October 9, 2008
Received: October 10, 2008

Dear Ms. DePouw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K081685

Device Name: LIAISON® HSV-1 Type Specific IgG and LIAISON® Control HSV-1 IgG

Indications For Use:

The LIAISON® HSV-1 Type Specific IgG assay is a chemiluminescent immunoassay (CLIA) to be used with the LIAISON® Analyzer for the qualitative determination of type specific IgG antibodies to Herpes Simplex Virus Type 1 (HSV-1) in human serum. The assay is indicated for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-1 infection.

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The LIAISON® Control HSV-1 (negative and positive) are intended for use as assayed quality control samples to monitor the performance of the LIAISON® HSV-1 Type Specific IgG assay.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081685